Registration Decision RD2015-17

Picoxystrobin

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Registration Decision for Picoxystrobin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Picoxystrobin (registration number 30469) and DPX-YT669 250FS Fungicide Seed Treatment, containing the technical grade active ingredient picoxystrobin, to control soil and seed-borne blackleg, seed borne *Alternaria* caused by *A. brassicae* in canola, rapeseed and mustards and the seedling disease complex (damping off, seedling blight, seed rot and root rot) caused by *Fusarium spp.* and *Rhizoctonia solani* in canola, rapeseed, mustards, corn and soybeans.

Picoxystrobin was previously registered in the end-use product Acapela Fungicide (Registration Number 30470) for foliar and soil applications to control a broad spectrum of fungal diseases in numerous crops.

The current products were proposed for registration in the consultation document[1] Proposed Registration Decision PRD2015-04, *Picoxystrobin*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for picoxystrobin and summarizes the Agency's decision, and the reasons for it. The PMRA received no comments on PRD2015-04, *Picoxystrobin*. This decision is consistent with the proposed registration decision stated in PRD2015-04, *Picoxystrobin.*

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-04, *Picoxystrobin* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Picoxystrobin?

Picoxystrobin is a quinone outside inhibitor class of fungicide that inhibits mitochondrial respiration. It is classified as a group 11 fungicide by the Fungicide Resistance Action Committee Picoxystrobin was previously registered in the end-use product Acapela Fungicide (registration number 30470) for foliar and soil applications to control a broad spectrum of fungal diseases in numerous crops. DPX-YT669 250FS Fungicide Seed Treatment is registered to control soil and seed-borne disease in canola, rapeseed, mustards, corn and soybeans.

Health Considerations

Can Approved Uses of Picoxystrobin Affect Human Health?

Picoxystrobin is unlikely to affect your health when used according to label directions.

Potential exposure to picoxystrobin may occur through the diet (food and water) or when handling and applying the product or when entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the technical grade active ingredient picoxystrobin was of moderate acute toxicity by the inhalation route and was mildly irritating to the eyes; consequently, the hazard signal words "WARNING – POISON" and "EYE IRRITANT" are required on the label. It was of low acute toxicity orally and dermally. Picoxystrobin was non-irritating to the skin and did not cause an allergic skin reaction.

The acute toxicity of DPX-YT669 250FS Fungicide Seed Treatment, was low via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes, slightly

irritating to the skin and did not cause an allergic skin reaction. No hazard signal words are required on the label.

Health effects in animals given repeated doses of picoxystrobin included irritation of the mucous membranes throughout the gastrointestinal tract. Picoxystrobin did not damage genetic material or cause cancer at doses that were relevant to human risk assessment. There was no indication that picoxystrobin caused damage to the immune system. Picoxystrobin did not cause birth defects in animals and there were no effects on reproduction. When picoxystrobin was given to pregnant or nursing animals, effects on the juvenile animal (decreased spleen weight) were observed at doses lower than those that were toxic to the mother, indicating that the young may be slightly more sensitive than the adult animal.

The risk assessment protects against the effects of picoxystrobin by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

Aggregate chronic dietary intake estimates (food plus drinking water) revealed that the general population and children (1-2 years), the subpopulation which would ingest the most picoxystrobin relative to body weight, are expected to be exposed to less than 3% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from picoxystrobin is not of health concern for all population sub-groups.

An aggregate acute dietary intake estimate (food and drinking water) for the highest exposed sub-population (all infants, <1 year old) used less than 1% (95^{th} Percentile, deterministic) of the acute reference dose, which is not a health concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

MRLs to cover residues of picoxystrobin in/on rapeseeds (canola), mustard seeds (oilseed type), soybean, field corn, sweet corn kernels plus cobs with husks removed, and popcorn grain have been specified based on residue data generated following foliar applications, for the detailed review see the Proposed Registration Decision PRD2012-10, *Picoxystrobin*. The seed treatment use of picoxystrobin on these crops is not expected to result in residues exceeding the established MRLs. The MRL recommended for picoxystrobin on mustard seeds (condiment type) is 0.08 ppm.

Occupational Risks From Handling DPX-YT669 250FS Fungicide Seed Treatment

Occupational risks are not of concern when DPX-YT669 250FS Fungicide Seed Treatment is used according to the label directions, which include protective measures.

Workers treating canola, rapeseed, mustard, soybean and corn seed with DPX-YT669 250FS Fungicide Seed Treatment in commercial seed treatment facilities and by commercial mobile treaters, and workers planting treated seed, can come into direct contact with picoxystrobin residues on the skin and through inhalation. Therefore, the label specifies that workers treating and handling treated seed must wear the following personal protective equipment. In commercial seed treatment facilities and commercial mobile treaters, workers mixing, loading, calibrating, treating, bagging, sewing, stacking, and forklifting treated seed must wear a long-sleeved shirt and long pants and chemical-resistant gloves. In addition, workers cleaning treatment equipment must wear coveralls over a long-sleeved shirt and long pants and chemical-resistant gloves. Workers planting treated seed must wear a long-sleeved shirt, long pants and chemical-resistant gloves.
Closed transfer is required for treating seeds in commercial settings and a closed cab tractor is required when planting treated seed. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to these individuals is not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Picoxystrobin Is Introduced Into the Environment?

When used as a seed treatment, picoxystrobin poses a negligible risk to terrestrial and aquatic organisms.

Picoxystrobin can enter the environment by dislodging from treated seed surfaces during and after seeding. When picoxystrobin enters aquatic systems it does not dissolve readily in water and will tend to move into sediments. Picoxystrobin is broken down by microbes in soils, sediments and water; thus, it is not expected to persist in the environment. The name and chemical structure of environmental transformation products of picoxystrobin are listed in Table 9 of the Proposed Registration Decision PRD2012-10, *Picoxystrobin*. Laboratory and field studies indicate that picoxystrobin and its transformation products are unlikely to move significantly downward through soils and reach groundwater. Picoxystrobin and its transformation products are not expected to carry over in important amounts into the next growing season. Picoxystrobin is not expected to accumulate in fish tissues. Picoxystrobin is not volatile and therefore not expected to be subject to long-range transport in the atmosphere.

Use of picoxystrobin as a seed treatment is expected to pose negligible risk to non-target terrestrial and aquatic organisms. No environmental risk was identified from exposure to the major transformation products of picoxystrobin.

Value Considerations

What Is the Value of DPX-YT669 250FS Fungicide Seed Treatment?

DPX-YT669 250FS Fungicide Seed Treatment, containing picoxystrobin, controls certain soil-borne and seed-borne diseases of canola, rapeseed, mustard, soybean and corn.

DPX-YT669 250FS Fungicide Seed Treatment controls certain soil-borne and seed-borne diseases (including damping-off, seedling blight, seed rot, and root rot caused by *Fusarium* spp., *Rhizoctonia solani;* soil-borne and seed-borne blackleg caused by *Leptosphaeria maculans*; and seed-borne *Alternaria* caused by *Alternaria brassicae*) of canola, rapeseed, mustard, soybean and corn. The registration of DPX-YT669 250FS Fungicide Seed Treatment will introduce a new active ingredient and an alternative product on the market to the growers.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of DPX-YT669 250FS Fungicide Seed Treatment to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with picoxystrobin on the skin or through inhalation of spray mists, anyone mixing, loading and applying DPX-YT669 250FS Fungicide Seed Treatment must wear the following PPE: For commercial treaters (facilities and mobile treaters), workers mixing, loading, calibrating, treating, bagging, sewing, stacking, and forklifting treated seed must wear a long-sleeved shirt and long pants and chemical-resistant gloves. In addition, workers cleaning treatment equipment must wear coveralls over a long-sleeved shirt and long pants and chemical-resistant gloves. Workers planting treated seed must wear a long-sleeved shirt, long pants and chemical-resistant gloves. Closed transfer is required for treating seeds commercially and a closed cab tractor is required when planting treated seed.

Environment

Although the potential of picoxystrobin exposure to aquatic organisms is negligible, a statement informing users of the toxicity of picoxystrobin to aquatic organisms is required on the product label.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-04, *Picoxystrobin*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.